Submitter:	Baxter Healthcare Corporation One Baxter Parkway Deerfield, Illinois 60015
	OCT 19 2006
Contact:	David E. Curtin Global Regulatory Affairs 1620 Waukegan Road, MPGR-AL McGaw Park, Illinois 60085 (847) 473-6079 (847) 785-5116 FAX
Date Prepared:	July 20, 2006
Device Name:	Trade Name: Xenium Common Name: Dialyzer Classification Name: High Permeability Hemodialysis System
Predicate Devices:	Baxter's Exeltra dialyzer, K030974 NxStage Medical's NxStage System One, K050525
Device Description:	Xenium dialyzers are polyethersulfone fiber dialyzers and will be labeled for single use only. The dialyzers are available in six sizes, which differentiate by membrane surface area. The polyethersulfone hollow fiber membrane is the same as that contained in NxStage System One cleared under NxStage Medical's premarket notification K050525. All other components in Xenium are the same as those contained in the Exeltra dialyzer cleared under Baxter's premarket notification K030974.
Intended Use:	Hemodialysis with Xenium dialyzers is indicated for patients with renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

Summary of Technological Characteristics Compared to Predicate Device:	The general design and materials of the Xenium dialyzer are the same as Exeltra dialyzer cleared under K030974 and NxStage System One dialyzer cleared under K050525, and do not raise any new types of safety and effectiveness issues when compared to the predicate devices.
Clinical Data:	Not Applicable
Performance:	Performance testing for Xenium dialyzers has been conducted in accordance with EN 1283 "Haemodialysers, Haemodiafilters, Haemofilters, Haemoconcentrators and their Extracorporeal Circuits," consistent with FDA guidance document titled "Guidance for the Content of Premarket Notifications for Conventional and High Permeability Hemodialyzers."
Conclusion:	The Xenium dialyzers are substantially equivalent to the currently cleared Exeltra and NxStage System One dialyzers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

OCT 19 2006

David E. Curtin, R.A.C.
Associate Director, Global Regulatory Affairs
Baxter Healthcare Corporation
Renal Division
1620 Waukegan Road, MPGR-AL
MCGAW PARK IL 60085

Re: K062079
Trade/Device Name: Xenium Dialyzer
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: July 20, 2006
Received: July 21, 2006

Dear Mr. Curtin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K062079

Device Name: Xenium Dialyzer

Indications For Use:

Hemodialysis with Xenium dialyzers is indicated for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

David A. Lepsen

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062079